UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF NORTH CAROLINA

UNITED STATES OF AMERICA, Plaintiff, v. ELK PHARMACY, INC., LARRY IRWIN, SUSAN BAKER, S. JASON COUCH, BETH PENCE, and LORI WYBLE, Defendants.	)	No. 24-CV-1006

CONSENT DECREE OF PERMANENT INJUNCTION

Plaintiff, the United States of America, by its undersigned attorneys, having brought an action against defendants Elk Pharmacy, Inc., ("Defendant Pharmacy"), and pharmacists Larry Irwin, Susan Baker, S. Jason Couch, Beth Pence, and Lori Wyble (collectively, "Defendants") seeking civil monetary penalties and injunctive relief for violations of the Controlled Substances Act, 21 U.S.C. § 801 *et seq.* (the "CSA");

Defendants having appeared in this action by their attorney, James A. Wilson, having waived service of process, and having consented to entry of this consent decree without contesting the allegations of the complaint;

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED as follows:

Jurisdiction and Venue

1. This Court has subject-matter jurisdiction over this action pursuant to 21 U.S.C. §§ 842(c)(1)(A), 843(f)(2), and 882(a), as well as 28 U.S.C. §§ 1345 and 1355.

2. Defendants each consent to this Court's subject-matter and personal jurisdiction over them.

3. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(b)(1) and (b)(2) because this is the district in which all the defendants reside and where a substantial part of the events or omissions giving rise to the claim occurred, and pursuant to 28 U.S.C. § 1395(a) because this is an action for recovery of a pecuniary fine or penalty and this is the venue where the action accrued or the defendant is found.

4. The United States alleges that Defendants have violated the CSA and its implementing regulations by failing to exercise their corresponding responsibility to ensure that the controlled substances they dispensed, helped dispense, or facilitated dispensing were issued for a legitimate medical purpose by a practitioner acting in the usual course of a practitioner's professional practice as required, *see* 21 C.F.R. § 1306.04, and by filling, helping fill or facilitating the filling of a prescription for a controlled substance outside the usual course of the professional practice of pharmacy as required by 21 C.F.R. § 1306.06.

5. Without answering or admitting these allegations and while denying any wrongdoing, Defendants agree that the United States' complaint states a claim for which civil monetary penalties may be awarded against them pursuant to 21 U.S.C. § 842(c) and for which the court may order injunctive relief pursuant to 21 U.S.C. §§ 843(f) and 882.

Civil Monetary Penalty

6. Defendants are jointly and severally liable for and shall pay to the United States a civil monetary penalty in the amount of Five Hundred Thousand Dollars

($500,000), pursuant to payment instructions to be provided by the United States. Defendants shall make an initial payment of Two Hundred and Fifty Thousand Dollars ($250,000) within fourteen (14) days of the entry of this Decree, and a second payment in the same amount within ninety (90) days of the first payment.

Injunctive Provisions

7. Upon entry of this decree, Defendants and each and all of their employees, agents, officers, directors who have any role or responsibility for the filling of controlled substance prescriptions are permanently restrained and enjoined under 21 U.S.C. §§ 843(f)(1) and 882, and the inherent equitable authority of this Court, from directly or indirectly dispensing, assisting in the dispensing, or otherwise facilitating the dispensing of any controlled substance as defined in the CSA or its implementing regulations, unless dispensing the prescription is in compliance with 21 U.S.C. § 842, 21 C.F.R. §§ 1306.04, 1306.06, or any of the North Carolina statutes and regulations pertaining to the dispensing of controlled substances.

Identification, Resolution and Documentation of Red Flags of Abuse or Diversion

8. To fulfill Defendants' obligations pursuant to the preceding paragraph, before dispensing or assisting in the dispensing of any controlled substance prescription, Defendants must for each prescription:

a. review the data available for the patient in question in the North Carolina prescription data monitoring program (the "PDMP") and reasonably determine from the information available from the PDMP, other records available

to Defendants, the prescription itself, and other circumstances surrounding the presentation of the prescription whether the prescription was issued for a legitimate medical purpose by an individual practitioner acting in the usual course of the practitioner's professional practice;

b. identify any indication that the prescribed controlled substance might not be for a legitimate medical purpose, or may be abused, misused, or otherwise diverted from legitimate uses, with such indications including *but not limited to* the following:

i. the patient returns too frequently, such that a prescription which should last for a given period of time when used legitimately is being refilled more frequently than medically indicated or directed for use;

ii. the patient is receiving prescriptions for antagonistic drugs, such as depressants and stimulants;

iii. the patient is receiving prescriptions for an opioid and a benzodiazepine within the same therapeutic period such that the patient could be taking both medicines concurrently;

iv. the patient presents prescriptions written in the names of other people;

v. the patient has traveled a long distance to the prescriber or the pharmacy;

vi. the patient has received the same or similar prescriptions from more than one prescriber;

vii. a number of people appear simultaneously, or within a short time, all bearing similar prescriptions from the same prescriber;

viii. people who are not regular patrons or residents of the community present prescriptions from the same prescriber;

ix. the prescriber writes significantly more prescriptions (or in larger quantities) compared to other practitioners in the same specialty in the area; or

x. the patient presents a prescription from a prescriber who is prescribing outside the scope of the prescriber's practice.

c. document in detail any indicators of abuse or diversion and the steps Defendants took to reasonably ensure that the prescription would not be abused or diverted for illegitimate purposes, and was issued for a legitimate medical purpose by a prescriber in the usual course of that prescriber's practice.

9. On the tenth business day of January 2025, Defendants shall submit to the Drug Enforcement Administration ("DEA") copies of all documentation called for under subparagraph c of the prior paragraph and subparagraph a of paragraph 12 below. Defendants shall submit this documentation thereafter on the tenth business day of January, April, July, and October during the duration of this Decree. At a minimum, this

documentation shall include, for each prescription filled despite the presence of indicators of abuse or diversion during the prior three-month period:

a. identification of the indicators of potential abuse or diversion;

b. a copy of the patient's PMDP data that the Defendants reviewed prior to filling the prescription; and

c. all documentation related to Defendants' determination that the prescription would not be abused or diverted for illegitimate purposes, and was issued for a legitimate medical purpose by a prescriber in the usual course of that prescriber's practice.

10. DEA's silence with regard to either documentation submitted by defendants or the absence of documentation shall not be construed as an indication that defendants properly filled the prescription in question. Nor shall DEA's silence be regarded as a waiver of any potential action DEA might take under the law or this decree.

Prohibition Against Filling Certain Prescriptions

11. As of the date the Court enters this Decree, Defendants shall not dispense, assist in dispensing, or otherwise facilitate dispensing a prescription for any Schedule II controlled substance for thirty (30) calendar days.

12. Notwithstanding anything else in this decree, Defendants shall not dispense, assist in dispensing, or otherwise facilitate dispensing a prescription for a controlled substance if Defendants know or should have known that dispensing the prescription would result in the patient receiving:

a. a daily dosage in excess of 90 milligram morphine equivalents if the prescription is taken as prescribed along with other prescriptions listed in the PDMP for the patient regardless of which pharmacy may have filled those prescriptions, unless the patient provides Defendants with documentation of a current hospice diagnosis or end-of-life care and Defendants provide this documentation to DEA pursuant to paragraph 9.b;

b. a combination of an opioid, a benzodiazepine, and carisoprodol or any other muscle relaxant;

c. a prescription for buprenorphine without naloxone (such as Subutex) without reliable documentation from the prescriber that the patient is pregnant, a nursing mother, or has had an actual adverse reaction to naloxone;

d. an early refill for any controlled substance;

e. any controlled substance whatsoever if the patient lives more than 30 miles driving distance from the Defendant Pharmacy;

f. any controlled substance if the patient is an employee of the Defendant Pharmacy; or

g. any controlled substance paid for with cash despite the fact that the patient has insurance available to pay for the patient's prescriptions.

13. If, at any time after entry of this decree, the DEA determines that any of the Defendants have failed to comply with any provision of this decree, DEA may, as and when it deems necessary, notify any or all of the Defendants in writing of the

noncompliance and order Defendants to take corrective action, including, but not limited to, ordering Defendants to immediately cease ordering, distributing, or dispensing controlled substances. This remedy shall be separate and apart from, and in addition to, any other remedy available to the United States under this decree or under the law, including additional civil monetary penalties.

14. The following process and procedures apply when the DEA issues an order under the preceding paragraph:

a. Defendants will implement the corrective action ordered by DEA without delay;

b. For any order calling on Defendants to cease ordering, distributing, or dispensing controlled substances, any and all DEA registrations under which Defendants have been operating or that Defendants otherwise maintain shall be deemed to have been surrendered for cause and Defendants will permit DEA immediate access to the Defendant pharmacy premise and permit DEA to seize all controlled substances and controlled substance order forms.

15. If any Defendant notifies DEA that he, she or it does not agree with any DEA order under the prior two paragraphs of this order and provides its reasons for such disagreement, DEA will review Defendant's notification and within 30 days thereafter, in writing, affirm, modify or withdraw its order, as DEA deems appropriate. If DEA affirms or modifies its order, it will explain the basis for its decision in writing. This written notification shall constitute final agency action.

a. If DEA affirms or modifies it order, Defendants may, within twenty-eight (28) calendar days, seek judicial review of the DEA's order in this Court. Defendants shall continue to diligently implement DEA's order while judicial review is pending unless and until the Court or any higher court reverses, stays or modifies DEA's order.

b. All decisions conferred upon DEA in this Decree shall be vested in DEA's discretion and, to the extent that these decisions are subject to review, shall be reviewed by the Court under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A). Review by the Court of any DEA decision rendered pursuant to this decree shall be based exclusively on the written record before DEA at the time the decision was made. No discovery shall be taken by any party.

16. If DEA orders any Defendant to cease ordering, distributing, or dispensing controlled substances under this decree, and that order is not otherwise reversed, then such Defendant shall be prohibited from seeking any further DEA registration, and any application for registration or subsequent registration issued shall be deemed null and void.

17. Representatives of DEA shall be permitted, without prior notice and as and when DEA deems necessary, to inspect Defendants' operations and, without prior notice, take any other measures necessary to monitor and ensure continuing compliance with the terms of this decree, the CSA, and all applicable regulations. During such inspections, DEA representatives shall be permitted to have immediate access to Defendants' places of business including, but not limited to all buildings, equipment, pharmaceuticals, computer

systems, and records, whether printed or digitally stored. Defendants will facilitate DEA's access to such items, records, or access to Defendants' computer systems. The inspections shall be permitted upon presentation of a copy of this decree and appropriate credentials. The inspection authority granted by this decree is separate from, and in addition to, the authority to inspect under the CSA.

18. Within five business days after entry of this decree, Defendants shall post a copy of this decree in the Defendant pharmacy in a location that will make it conspicuous to all Defendants and individuals with any responsibility for filling or assisting with the filling of prescriptions at the Defendant pharmacy and shall ensure that the decree remains posted for as long as the decree remains in effect. Within ten business days after entry of this decree, Defendants shall provide to DEA an affidavit, from a person with personal knowledge of the facts stated therein, stating the fact and manner of compliance with this paragraph.

19. Within ten business days after entry of this decree, Defendants shall provide a copy of this decree by personal service, email (with delivery confirmation), or certified mail (return receipt requested) to each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons or entities in active concert or participation with any of them ("Associated Persons"). Within twenty (20) business days after entry of this decree, Defendants shall provide to DEA an affidavit, from a person with personal knowledge of the facts stated therein, stating the fact and manner of compliance with this paragraph, identifying the names, addresses, and

positions of all Associated Persons who have received a copy of this decree, and attaching a copy of the executed certified mail return receipts or email delivery confirmation, as applicable.

20. In the event that any of the Defendants becomes associated with any additional Associated Person(s) at any time after entry of this decree, Defendants shall immediately provide a copy of this decree, by personal service, email (with delivery confirmation), or certified mail (return receipt requested) to such Associated Person(s). Within ten (10) business days after of any of the Defendants becomes associated with any additional Associated Person, Defendants shall provide to DEA an affidavit, from a person with personal knowledge of the facts stated therein, stating the fact and manner of compliance with this paragraph, identifying the names, addresses, and positions of all Associated Persons who received a copy of this decree pursuant to this paragraph, and attaching a copy of the executed certified mail return receipts, or email delivery confirmation, as applicable.

21. Defendants shall notify DEA in writing at least 42 calendar days before any change in the ownership, name, or character of their business that occurs after entry of this decree, including any proposed sale, incorporation, reorganization, creation of a subsidiary, relocation, dissolution, bankruptcy, assignment, or any other change in the structure or identity of Defendant Pharmacy, or the sale or assignment of any business assets, such as buildings, equipment, or inventory, that may affect obligations arising out of this decree. Defendants shall provide a copy of this decree to any prospective purchaser, successor or

assignee at least 35 calendar days prior to any sale or assignment. At its option, DEA may require Defendants to secure the agreement of any prospective purchaser, successor or assignee of significant assets of the Defendant Pharmacy to be bound by this consent decree as a condition of any sale, transfer, assignment or change in ownership of significant assets of Defendant Pharmacy. Defendants shall furnish DEA with an affidavit of compliance with this paragraph no later than 21 calendar days prior to such sale, transfer, assignment or change in ownership.

22. Should the United States bring and prevail in a contempt action to enforce the terms of this decree, Defendants shall, in addition to other remedies, reimburse the United States for its attorneys' fees (including overhead), expert witness fees, travel expenses incurred by attorneys and witnesses, investigational and analytical expenses, administrative and court costs, and any other costs or fees relating to such contempt proceedings.

23. All notifications, correspondence, and communications to DEA required by the terms of this decree shall be prominently marked "Decree Correspondence" and delivered by electronic mail and/or hard copy to DEA Diversion Investigator Heidi S. Crater, 1801 Stanley Road, Suite 204, Greensboro, North Carolina 27407, Heidi.s.crater@usdoj.gov, the United States Attorney for the Middle District of North Carolina, attention Assistant U.S. Attorney Cassie Crawford, 101 Edgeworth Street, 4th Floor, Greensboro, North Carolina 27401, cassie.crawford@usdoj.gov, and shall reference this civil action by case name and number. All notifications, correspondence and

communications to Defendants from United States of America and/or DEA under this decree, shall be prominently marked "Decree Correspondence" and shall be delivered to Defendants by electronic mail at elkrx@rivercto.net (Elk Pharmacy and Larry Irwin), mcsbbakers@aol.com (Susan Baker), lrwyble@yahoo.com (Lori Wyble), batreepharm@gmail.com (Beth Pence), and sjcouch72@hotmail.com (Jason Couch), and hard copy to: Elk Pharmacy, Inc., 116 E. Main St., Elkin, NC 28621 and their attorneys Amy G. Fitzhugh, Jordan M. Spanner, and James A. Wilson, Ward and Smith, P.A., Post Office Box 33009, Raleigh, NC 27636-3009, agfitzhugh@wardandsmith.com, jmspanner@wardandsmith.com, and jawilson@wardandsmith.com.

24. No sooner than 5 years after entry of this decree, Defendants may petition this Court for relief from this decree. If Defendants have maintained a state of continuous material compliance with this decree, the CSA and its implementing regulations, and any North Carolina statutes and regulations pertaining to the distribution of controlled substances during the 5 years preceding Defendants' petition, the United States will not oppose such petition.

25. This Court retains jurisdiction over this action and the parties thereto for the purpose of enforcing and modifying this decree and for the purpose of granting such additional relief as may be necessary or appropriate.

SO ORDERED, this 4th day of December, 2024.

Thomas A. Schmedl

UNITED STATES DISTRICT JUDGE

Entry consented to:

For Defendants

LARRY IRWIN
On behalf of Elk Pharmacy, Inc.

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Individually

SUSAN BAKER
Individually

S. JASON COUCH
Individually

BETH PENCE
Individually

LORI WYBLE
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Individually

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